

PSJ3

Exhibit 16

2008 GOALS

EMPLOYEE: BRIAN M. CHERICO
POSITION: MANAGER, REGULATORY AFFAIRS & HEALTHCARE POLICY
FOR PERIOD: FEBRUARY 15 – DECEMBER 31, 2008
REVISED: LCH 7/14/08, BC 7/15/08, LCH & AD 7/18/08

GOAL: Prepare and submit written comments and testimony to CMS, FDA, DEA and other agencies as appropriate, for public record, defining HDMA positions on proposed and interim administrative rules, and work with outside counsel or other third parties as required. **STATUS:** The following comments have been written this year:

1. **Proposed Rule DEA-303-P; Format changes to DEA Order Form 222, for Schedule I and II controlled substances (1/28/08)**
2. **Comments to US Sentencing Commission's Notice of Proposed Amendments to Federal Sentencing Guidelines (3/27/08)**
3. **Comments to Interim Final Rule CMS-2238-IFC; Medicaid program, Multiple Source Drug Definition (4/14/08)**
4. **Comments to HHS Guidance on Pandemic Influenza Employer Antiviral Stockpiling (7/3/08)**

GOAL: Follow up all association actions subsequent to the filing of the HDMA written comments to the AMP final rule. Monitor HHS/CMS developments re: AMP reimbursement and related issues since filing of final rule comments. Keep Reimbursement Task Force notified of federal regulatory and legislative initiatives concerning AMP, as warranted; maintain contact with RTF Chairman.

STATUS:

1. **Filed multiple source rule comments as addendum to final AMP rule comments.**
2. **Conducted RTF telecons on status of AMP final rule before and after filing multi-source rule comments.**

GOAL: Track regulatory/legislative activities of "Rump Group" coalition of pharmacy trade groups and other interested stakeholders; coordinate support and communications on fixing AMP with Congress

STATUS: Contributed to the drafting of two Coalition letters sent to the Hill regarding need for legislative changes to AMP.

GOAL: Monitor the pending AMP litigation filed against HHS/CMS and communicate all lawsuit and related developments.

STATUS: Developments since last review:

1. **Assumed primary responsibility for tracking pending NACDS /NCPA lawsuit filed against HHS.**
2. **Coordinated communication of news about lawsuit, developments with outside counsel (Artur Tsien, Esq.) on an ongoing basis, as needed.**
3. **Maintained a summary analysis document of suit and its status for internal use.**
4. **Provided updates on status of litigation during committee/task force teleconferences.**

GOAL: Increase coordination activities with SGAC on upcoming AMP regulatory activities on the state level; identify priorities for consideration.

STATUS:

1. **Coordinated efforts on NY bill regarding priority of seasonal flu vaccine distribution to physicians' offices.**
2. **Resolved member issue with explanation on the applicability and use of the NPI as a provider identifier instead of using DEA numbers, which were not intended to be used as an identifier for certain provider information.**

GOAL: Provide AMP regulatory and litigation update reports during SGAC teleconferences/outreach with other AMP stakeholders, pharmaceutical industry trade associations and key officials at CMS, HHS, and other federal agencies.

STATUS: Contacts since last review:

1. **Paul Kelly, NACDS (Rump Group)**
2. **Lauren Randle, Esq. Sidley Austin LLP**
3. **Staffer of US Federal Sentencing Commission**
4. **Brent Sullivan, US Oncology**
5. **Saundra Daunt, SRD Advisory Group**
6. **Rebecca Shanahan, SCV**

GOAL: Develop strategies, options and alternatives to respond to DEA concerns about the security of controlled substances in-transit. **STATUS: Attended NABP Task Force meeting on In-transit losses in April 2008. Communicated members' position on current industry security protocols in place to combat in-transit losses in the supply chain. Created a summary document of current industry practices to secure against in-transit losses. Subsequent NABP Task Force report recognized current industry security procedures, and recommended no additional requirements for distributors.**

GOAL: Continue to provide staff support to HDMA efforts to participate in the development of industry practices, procedures, guidelines or other solutions that meet DEA criteria for the handling of suspicious orders of controlled substances by member distributors; provide equivalent support for compliance with industry self-certification requirements, and other issues that may develop in 2008 related to maintaining the security of controlled substances by HDMA members. **STATUS: Have maintained ongoing supporting role.**

GOAL: Continue to enhance role as lead staff member to the Reimbursement Task Force. Strive to establish appropriate agenda, identify priorities for RTF consideration, and work with ITF, FGAC, RAC and SGAC to develop policies consistent with industry goals. Priorities include but are not limited to AMOP and ASP initiatives. **STATUS: Continue to deliver report updates to above committees and task forces as lead HDMA spokesperson on AMP regulatory developments and pending litigation.**

GOAL: Strive to identify and participate in the presentation of at least one educational session on a federal regulatory issue of importance and value to HDMA staff or members. **STATUS: Have discussed plans to present update on AMP final rule when courts resolve the status/applicability of the rule (pending). Worked with Larri Short on DMC session on CMS update.**

GOAL: Work with Industry Relations staff to coordinate with the Rx Response Coalition Work Group, to create strategies and complete tasks required of HDMA concerning Emergency Preparedness and Response to both natural/man-made disasters and pandemic influenza. Advance the use and visibility of information contained in the list of distribution members on the HDMA website to the Rx Response program.

STATUS: Participated and contributed with IR and MAC in ongoing series of meetings regarding emergency response preparedness with PhRMA and other stakeholders. Also represented HDMA in live Rx Response Emergency Response exercises in coordination with PhRMA and Heather Zenk (AmerisourceBergen).

GOAL: Continue role as the main staff contact with the CDC and National Flu Summit on seasonal influenza vaccine supply issues; Work with outside stakeholders and SGA staff on developing formal HDMA positions to educate state governments about the distribution of seasonal influenza vaccines, when necessary.

STATUS: Maintained contact with National Flu Summit during periodic teleconferences, and communicate their activities re: distribution to our members (IVATS program).

GOAL: Support the coordination of Influenza Task Force (ITF) activities. Strive to identify additional objectives in partnership with HHS or other federal authorities on vaccine and antiviral distribution strategies. Develop policies and provide information on distribution industry and or practices as needed to meet government and distributor objectives. **STATUS: No activity this year, thus far.**

GOAL: Continue to network and build relationships with members healthcare trade association representatives as well as representatives of other segments of the wholesale distribution and related industries; continue to share latest developments on Medicaid AMP and CMS with "Rump Group" (NACDS, GPhA, NCPA)

STATUS: Have established relationships with:

1. Don Bell, General Counsel, NACDS
2. Mary Ellen Kleiman, AGC, NACDS
3. Paul Kelly, NACDS
4. Also contributed to the drafting and editing of two Coalition letters sent to the Hill regarding legislative changes needed to AMP.

GOAL: Enhance issue knowledge by attending workshops, conferences, receptions, Continuing Legal Education seminars and related events and meeting with industry experts and representatives from federal agencies, with management support.

STATUS: No industry seminars planned at this time, CLE classes planned fall 2008.